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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,433	10/24/2003	Arthur H. Konwinski	SP-1309	2019

44388 7590 10/19/2004

SOLAE, LLC
P. O. BOX 88940
ST. LOUIS, MO 63188

EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,433	KONWINSKI ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The antecedent basis for "the precipitate" is unclear. In claim 1 there are two precipitates formed. It is unclear which of these precipitates is being referred to in claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5-7, 10, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,505,946.

The claims are drawn to a method of making a Bowman-Birk inhibitor from soybeans. Claim 1 has five steps. For ease, these steps will be referred to as steps A-E. Step A requires the starting material to be acid extracted solubles from defatted soybean material. Step B mixes these solubles with acetone to form a precipitate. Step C separates the precipitate. Step D

dilutes the precipitate in water. Step E then ultrafilters the diluted precipitate. Claim 3 requires that the acetone-precipitate mixture in step B is agitated and then allowed to settle. Claim 5 requires that the defatted soybean material from step A is from flakes or flour. Claim 6 requires that the defatted soybean material is slurried with water. Claim 7 requires that the slurry from claim 6 is adjusted to a pH of 4.0 to 6.5 using HCl. Claim 10 requires that the acetone used in step B is half to 4 times the weight of the acid extracted solubles. Claim 14 specifies that the retentate from step E is dried. Claims 15 and 16 are drawn to products produced by the process of claim 1 or 7.

US '946 teaches a method of making a Bowman-Birk inhibitor from soybeans. Example 1 in columns 12 and 13 teaches a specific method that anticipates applicant's claims. In this example, defatted soybean flour is mixed with HCl to adjust the pH to 5.3 (this step corresponds to applicant's step A in claim 1 and claims 5-7). Acetone is then acid extracted solubles. About a 2:1 acetone to solubles ratio is used. The mixture is stirred and allowed to settle (these steps correspond to applicant's step B and claims 3 and 10). The precipitate is then separated (this corresponds to applicant's step C). The precipitate is then diluted with water (this corresponds to applicant's step D). The diluted precipitate is then ultrafiltered (this corresponds to applicant's step E). The concentrated product is then dried to produce the purified Bowman-Birk inhibitor (corresponds to applicant's claim 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 4-13, and 16-20 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,505,946.

The method taught by US '946 is discussed above. The specific process taught by Example 1 of this reference is the example that meets the largest majority of applicant's limitations. However, this reference teaches numerous embodiments that show that the specific process for extracting a Bowman-Birk inhibitor can be varied in a variety of manners in order to optimize the production of the inhibitor. Specifically, the reference does not teach using two acetone extractions in Example 1, but teaches that two acetone extractions can be utilized in the extraction of the inhibitor (see Example 7). Thus, a person of ordinary skill in the art would reasonably expect that two acetone extractions could be used in the method of Example 1 in order to achieve a larger amount of extraction of acetone insoluble components from the soybean. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to add an additional acetone extraction step to the method of Example 1.

The reference also teaches that vacuum filtration can be utilized to separate a precipitate from the liquid (see Examples 2 and 3). Thus, this is a technique known to be useful in separating precipitates from liquids after an extraction and would be obvious to employ for this purpose in the method taught by Example 1.

In addition, Example 1 does not specifically teach using all of the amounts of acetone claimed by applicant. However, the subsequent examples use a variety of amount of acetone.

Thus, the amount of acetone is a variable that can be optimized in order to best achieve the extraction of the acetone insoluble components from the soybean.

The reference also does not specifically teach agitating the acid/soybean slurry for an hour or using all of the acid pH's claimed by applicant. However, the pH and mixing time for an extraction procedure are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of creating acid extracted solubles from defatted soybean. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference does not specifically teach a Bowman-Birk inhibitor with the protein and chymotrypsin inhibitor activity claimed. However, as discussed above, the reference is considered to teach a method for making a Bowman-Birk inhibitor that meets all the limitations of applicant's claims. Thus, since the prior art teaches a method that is the same as claimed, the product resulting from this method would naturally have the same characteristics as claimed.

5. Claims 1-20 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/197,297 in view of US Pat. No. 5,505,946. Application '297 has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Application '297 also claims extracting a Bowman-Birk inhibitor from acid extracted soybeans using acetone extractions using the same steps as claimed by applicant. However, Application '297 does not teach using an ultrafiltration step. However, as discussed above, US '946 teaches that ultrafiltration is an effective means of isolating a Bowman-Birk inhibitor from a soybean extraction. Based on this teaching by US '946, a person of ordinary skill in the art would reasonably expect that the method taught by Application '297 could beneficially be modified to include an ultrafiltration step. Based on this reasonable expectation of beneficial results, an artisan would be motivated to make this modification.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/197,297 in view of US Pat. No. 5,505,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because as discussed above, taken together, Application '297 and US '946 are considered to teach the claimed method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe, Examiner
October 14, 2004